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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/326,285	06/07/1999	JENNIE BIH-JIEN SHEN	BB-1137	4005

23906 7590 09/04/2003

E I DU PONT DE NEMOURS AND COMPANY
LEGAL PATENT RECORDS CENTER
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4417 LANCASTER PIKE
WILMINGTON, DE 19805

EXAMINER

SWITZER, JULIET CAROLINE

ART UNIT	PAPER NUMBER
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1634

DATE MAILED: 09/04/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/326,285	SHEN, JENNIE BIH-JIEN	
	Examiner	Art Unit	
	Juliet C. Switzer	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 May 2003.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 172-176 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 172-176 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 28 May 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-946) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>05/03</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. This action is written in response applicant's correspondence 5/28/03. Claims 172-176 were amended. Claims 172-176 are pending and are examined herein. Applicant's amendments and arguments have been thoroughly reviewed, but are not fully persuasive for the reasons that follow. Any rejections not reiterated in this action have been withdrawn. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

This action is FINAL.

Priority

2. Applicant's claim for domestic priority under 35 U.S.C. 119(e) is acknowledged. However, the provisional application upon which priority is claimed fails to provide adequate support under 35 U.S.C. 112 for claims 172-176 of this application. Priority is not granted to provisional application 60/088987 because the provisional does not provide descriptive support for nucleic acids that have 90% identity or that are fragments of 500 or more nucleotides.

Drawings

3. Corrected drawing were filed and are approved for examination.

Claim Rejections - 35 USC § 112

Second Paragraph

4. Claims 172-176 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The previous rejections under 112 2nd paragraph are withdrawn in light of applicant's extensive amendments to the claims. New rejections are set forth to address the amended claims.

Claims 172, 174, 175, and 176 are indefinite over the recitation "or a subsequence of SEQ ID NO: 9 having at least 500 nucleotides" because SEQ ID NO: 9 is an amino acid sequence and does not have any nucleotides. It is not clear if applicant is trying to set forth a chimeric gene comprising an isolated nucleic acid fragment that encodes a subsequence of SEQ ID NO: 9, wherein the nucleic acid fragment has at least 500 nucleotides or if applicant is setting forth that the subsequence of SEQ ID NO: 9 has 500 nucleotides.

First Paragraph

5. The rejection for lack of enablement is withdrawn in light of applicant's extensive amendments to the claims which change the nature of the method (to a method of feeding), the scope of the recited transgenic plants, and the scope of the promoters being used.
6. Claims 172-176 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The current claims are drawn to a method which improving animal carcass quality which comprise feeding the animal feed derived from transgenic plants comprising chimeric molecules which comprise nucleic acids encoding a corn delta-9 stearoyl ACP desaturase which has an amino acid sequence with 90% identity to SEQ ID NO: 9, nucleic acids encoding a corn delta-12 desaturase wherein the nucleic acid has 90% sequence identity to SEQ ID NO: 1. This large genus is represented in the specification by only the nucleic acid encoding SEQ ID NO: 9 or by

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SEQ ID NO: 1. Further, the response of the plants produced largely depends on the functionality of the sequence introduced. Thus, applicant has express possession of only single species in a genus which comprises thousands of different possibilities.

With regard to the written description, all of these claims encompass nucleic acid sequences different from those disclosed in the specific SEQ ID No:s which, for claims 172-176 include modifications by permitted by the % identity language for which no written description is provided in the specification. Furthermore, the claims all recite that the nucleic acids at issue are "corn" nucleic acids, and the specification has provided no guidance as to how to identify, of all of the nucleic acids encompassed within the breadth of these claims, which of these are particularly "corn" nucleic acids encoding "corn" enzymes.

It is noted that in Fiers v. Sugano (25 USPQ2d, 1601), the Fed. Cir. concluded that

"...if inventor is unable to envision detailed chemical structure of DNA sequence coding for specific protein, as well as method of obtaining it, then conception is not achieved until reduction to practice has occurred, that is, until after gene has been isolated...conception of any chemical substance, requires definition of that substance other than by its functional utility."

In the instant application, only the nucleic acids encoding SEQ ID NO: 9 and the nucleic acid SEQ ID NO: 1 are described. Also, in Yas-Cath Inc. v. Mahurkar (19 USPQ2d 1111, CAFC 1991), it was concluded that:

"...applicant must also convey, with reasonable clarity to those skilled in art, that applicant, as of filing date sought, was in possession of invention, with invention being, for purposes of "written description" inquiry, whatever is presently claimed."

In the application at the time of filing, there is no record or description which would demonstrate conception or written description of any plants containing chimeric genes modified

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by addition, insertion, deletion, substitution or inversion with the disclosed SEQ ID Nos but retaining correlative function in the claimed product. It is noted that the claims recite that the nucleic acid fragment must encode either a corn delta-9 stearoyl ACP desaturase or a corn delta-12 desaturase, but the claims do not set forth that this desaturase have desaturase activity, and thus the claims do not clearly set forth a structure/function relationship for the claimed nucleic acids.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claims 172 and 176 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hitz *et al.* (US 5443974) in view of Zwick *et al.* (US 6350934).

Hitz *et al.* teach transgenic soybeans that have an increased stearic acid content (18:0 fatty acids; see Col. 34), and teach that the seeds containing increased stearic acid have "improved oil" and would be valuable as animal feed (Col. 2, lines 26-27). Hitz *et al.* do not teach a method of feeding an animal, or in particular feeding an animal a corn grain from a transgenic plant as described in claim 172.

Zwick *et al.* teach a transgenic corn plant comprising a chimeric gene comprising an isolated nucleic acid fragment encoding a corn delta-9 stearoyl ACP desaturase wherein said desaturase has an amino acid sequence of at least 90% based on the Clustal method of alignment when compared to SEQ ID NO: 9 (plant described in claim 172(i)). Specifically, Zwick *et al.*

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teach a corn plant transformed with maize delta-9 desaturase in the antisense orientation relative to the promoter (Col. 30-32). Zwick *et al.* teach the grain (seed) of such plants (Col. 32, lines 32-34). Zwick *et al.* teach that plants expressing the antisense delta-9 desaturase have high stearic acid phenotype (Col. 43-47). An alignment of the instant SEQ ID NO: 9 against the desaturase encoded by SEQ ID NO: 1 of Zwick *et al.* is provided, showing an alignment score of 97%. The top line is the sequence from Zwick *et al.* and the bottom line is instant SEQ ID NO:

9.

CLUSTAL W (1.82) Multiple Sequence Alignments

Sequence type explicitly set to Protein

Sequence format is Pearson

Sequence 1: zwick 393 aa

Sequence 2: seq 391 aa

Start of Pairwise alignments

Aligning...38000.000000 393 391

Sequences (1:2) Aligned. Score: 97

Guide tree file created: [/tmp/2111.dnd]

Start of Multiple Alignment

There are 1 groups

Aligning...

Group 1: Sequences: 2 Score:6189

Alignment Score 2359

CLUSTAL-Alignment file created [/tmp/2111.out]

CLUSTAL W (1.82) multiple sequence alignment

```
zwick      MALRLNDVALCLSPPLAARRRRSSGRFVAVASMT-SAVSTKVENKKPFAPPREHVQVT
seq        MALRLHDVALCLSPPLAARRR--SGGSFVAVASMTSAAVSTRVENKKPFAPPREHVQVT
          *****
zwick      HSMPPHKIEIFKSLDDWARDNILTHLKPVEKWCWQPQDFLPDPASEGFHDEVKELRERAKE
seq        HSMPSHKIEIFKSLDDWARDNILTHLKPVEKWCWQPQDFLPDPASEGFHDEVKELRERAKE
          ****
zwick      IPDDYFVCLVGDMITEEALPTYQTMNLTLDGVRDETGASPTAWAVWTRAWTAEENRHGDL
seq        IPDDYFVCLVGDMITEEALPTYQTMNLTLDGVRDETGASPTAWAVWTRAWTAEENRHGDL
          *****
zwick      LNKYMYLTGRVDMRQIEKTIQYLLIGSGMDPRTENNPYLGFYITSFQERATFISHGNTARH
seq        LNKYMYLTGRVDIRQIEKTIQYLLIGSGMDPRTENNPYLGFVYTSFQERATFISHGNTARH
          *****
zwick      AKDFGDLKLAQICGIIASDEKRHETAYTKIVEKLFEDPDGTVVALADMMRKKISMPAHL
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seq          AKDFGDLKLAQICGIIASDEKRHETAYTRIVEKLFEIDPDGTVVADMMKKKISMPAHL
              *****;*****
zwick
seq          MFDGQDDKLFHFMSMVAQRLGVYTARDYADILEFLVDRWKVASLTGLSGEGNKAQDYLCT
              MFDGQDDKLFHFMSMVAQRLGVYTARDYADILEFLVDRWKVALTG-LSGEGNKAQDYLCT
              *****
zwick
seq          LASRIRRLERAQSRRAKAGTLPFSSWVYGRDVQL
              LASRIRRLDERAQSRRAKAGTLPFSSWVYGREVQL
              *****;*****

```

It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have combined the teachings of Hitz *et al.* in view of Zwick *et al.* and to have produced a method for feeding an animal which comprises a step feeding the animal the transgenic corn grain taught by Zwick *et al.* One would have been motivated to provide such a method in view of the teachings of Hitz *et al.* that foods with increased stearic acid content are desirable as food stuffs, and the teachings of Zwick *et al.* which provide such transgenic corn grains.

9. Claims 173 and 176 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hitz *et al.* (US 5443974) in view of both Lightner *et al.* (WO 94/11516) and Zwick *et al.* (US 6350934).

The rejected claims are drawn to a method of feeding an animal comprising feeding an animal a corn grain obtained from a transgenic corn plant comprising in its genome a chimeric gene comprising an isolated nucleic acid fragment encoding a corn delta-12 desaturase wherein said fragment has a nucleic acid sequence identity of at least 90% based on the Clustal method of alignment when compared to instant SEQ ID NO: 1 operably linked to at least one regulatory sequence, wherein expression of the chimeric gene results in an altered corn oleic acid phenotype.

Hitz *et al.* teach transgenic soybeans that have modified oil content (see Col. 34), and teach that the seeds containing modified oil content would be valuable as animal feed (Col. 2, lines 26-27). Hitz *et al.* further teach that oleic acid is an unsaturated fatty acid (Col. 1, lines 36-37), and that diets high in monounsaturated fat may reduce the effects of "bad" cholesterol (Col. 1, lines 50-55). Hitz *et al.* do not teach a method of feeding an animal, or in particular feeding an animal a corn grain from a transgenic plant.

Lightner *et al.* teach transgenic plants comprising in their genome an isolated nucleic acid fragment encoding a delta-12 desaturase (Example 6, beginning on page 83 provides such soybean plants). Lightner *et al.* teach that these plants have altered corn oleic acid content, specifically an increased 18:1 oil content (p. 95). Lightner *et al.* teach the nucleotide sequence encoding a corn delta-12 desaturase, and the nucleotide sequence taught by Lightner *et al.* is 100% identical to instant SEQ ID NO: 1 (see SEQ ID NO: 7 of Lightner *et al.*, and pages 75-77). Lightner *et al.* specifically suggest the transformation of corn plants (p. 10, line 33, for example), but do not exemplify transgenic corn plants.

Zwick *et al.* specifically exemplify making transgenic corn plants (Col. 30-32, for example).

Thus, given the teachings of Lightner *et al.* in view of Zwick *et al.*, it would have been prima facie obvious to have produced transgenic corn plants comprising an isolated nucleic acid fragment encoding a corn delta-12 desaturase, wherein the fragment is SEQ ID NO: 7 as taught by Lightner *et al.*, which fragment has is identical to instant SEQ ID NO: 1. The ordinary practitioner would have been motivated to have produced such plants by the specific suggestion of Lightner *et al.* to produce such transgenic corn plants, by Lightner *et al.*'s success at

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modifying the oleic oil content of both soybean and canola plants, and a desire to extend such methods to corn plants. The ordinary practitioner would have been further motivated by the fact that Zwick *et al.* exemplify successful transformation of corn plants, and thus one would have had an expectation of success.

Given the combined teachings of Hitz *et al.*, Zwick *et al.*, and Lightner *et al.*, it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have produced a method of feeding for feeding an animal which comprises a step feeding the animal the transgenic corn grain taught by Lightner *et al.* in view of Zwick *et al.* One would have been motivated to provide such a method in view of the teachings of Hitz *et al.* in order to take reap the possible health benefits of consuming corn grain with increased levels of the "good" monounsaturated fatty acid oleic acid in view of the teachings of Hitz *et al.*

10. Claim 174 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hitz *et al.* in view of Lightner *et al.* and Zwick *et al.* as applied to claims 173 and 176 above, and further in view of Kossman *et al.* (WO 95/07355).

The rejected claim is drawn to a method of feeding an animal comprising feeding the animal a corn grain obtained from a transgenic corn plant comprising in its genome a chimeric gene comprising an isolated nucleic acid fragment encoding a corn delta-9 stearyl ACP desaturase wherein said desaturase has an amino acid sequence identity of 90% based on the clustal method of alignment when compared to SEQ ID NO: 9, and linked to a second chimeric gene encoding a corn delta-12 desaturase wherein said fragment has a nucleic acid sequence identity of at least 90% based on the clustal method of alignment when compared to a nucleic

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acid as set forth in SEQ ID NO: 1, operably linked to at least one regulatory sequence, wherein the expression of the chimeric gene results in an altered corn oil phenotype.

The teachings of Hitz *et al.*, Lightner *et al.*, and Zwick *et al.* are applied to claim 174 as the previously were applied to claims 173 and 176. These do not provide a method for feeding an animal a corn from a transgenic plant with both constructs having both a delta-9 and delta-12 desaturase.

Hitz *et al.* further teach transgenic soybeans that have an increased stearic acid content (18:0 fatty acids, see Col. 34), and teach that the seeds containing increased stearic acid have "improved oil" and would be valuable as animal feed (Col. 2, lines 26-27).

Zwick *et al.* further teach a transgenic corn plant comprising a chimeric gene comprising an isolated nucleic acid fragment encoding a corn delta-9 stearoyl ACP desaturase wherein said desaturase has an amino acid sequence of at least 90% based on the Clustal method of alignment when compared to SEQ ID NO: 9 (plant described in claim 172(i)). Specifically, Zwick *et al.* teach a corn plant transformed with maize delta-9 desaturase in the antisense orientation relative to the promoter (Col. 30-32). Zwick *et al.* teach the grain (seed) of such plants (Col. 32, lines 32-34). Zwick *et al.* teach that plants expressing the antisense delta-9 desaturase have high stearic acid phenotype (Col. 43-47). An alignment of the instant SEQ ID NO: 9 against the desaturase encoded by SEQ ID NO: 1 of Zwick *et al.* is provided, showing an alignment score of 97%. The top line is the sequence from Zwick *et al.* and the bottom line is instant SEQ ID NO: 9.

CLUSTAL W (1.82) Multiple Sequence Alignments

Sequence type explicitly set to Protein

Sequence format is Pearson

Sequence 1: zwick 393 aa

Sequence 2: seq 391 aa

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Start of Pairwise alignments
Aligning...38000.000000 393 391

Sequences (1:2) Aligned. Score: 97
Guide tree file created: [/tmp/2111.dnd]
Start of Multiple Alignment
There are 1 groups
Aligning...
Group 1: Sequences: 2 Score:6189
Alignment Score 2359
CLUSTAL-Alignment file created [/tmp/2111.out]
CLUSTAL W (1.82) multiple sequence alignment

```

zwick      MALRLNDVALCLSPPLAARRRRSSGRFVAVASMT-SAVSTKVENKKPFAPPREHVHVQVT
seq         MALRLHDVALCLSPPLAARRR--SGGSFVAVASMTSAAVSTRVENKKPFAPPREHVHVQVT
          *****;***** *.* ***** ;****;*****

zwick      HSMPPHKIEIFKSLDDWARDNILTHLKPVEKWCWQPQDFLPDPASEGFHDEVKELRERAKE
seq         HSMPSHKIEIFKSLDDWARDNILTHLKPVEKWCWQPQDFLPDPASEGFHDEVKELRERAKE
          ****.*****

zwick      IPDDYFVCLVGDMITTEALPTYQTMNLTLDGVRDETGASPTAWAVWTRAWTAEENRHGDL
seq         IPDDYFVCLVGDMITTEALPTYQTMNLTLDGVRDETGASPTAWAVWTRAWTAEENRHGDL
          *****

zwick      LNKYMYLTGRVDMRQIEKTIQYLLIGSGMDPRTENNPYLGFIYTSFQERATFISHGNTARH
seq         LNKYMYLTGRVDIRQIEKTIQYLLIGSGMDPRTENNPYLGFIYTSFQERATFISHGNTARH
          *****;*****;*****;*****

zwick      AKDFGDLKLAQICGIIASDEKRHETAYTKIVEKLFEIDPDGTVVALADMMRKKISMPAHL
seq         AKDFGDLKLAQICGIIASDEKRHETAYTKIVEKLFEIDPDGTVVALADMMKKKISMPAHL
          *****;*****

zwick      MFDGQDDKLFHFMSVQAQLGVYTARDYADILEFLVDRWKVASLTGLSGEGNKAQDYLCT
seq         MFDGQDDKLFHFMSVQAQLGVYTARDYADILEFLVDRWKVALTG-LSGEGNKAQDYLCT
          *****

zwick      LASRIRRLERAQSRRAKKAGTLPFSWVYGRDVQL
seq         LASRIRRLDERAQSRRAKKAGTLPFSWVYGREVQL
          *****;*****;***

```

Finally, at the time the invention was made it was routine in the art to place two different genes or gene fragments (in the sense or anti-sense orientation) on the same construct in order to achieve the effects of both fragments. This practice is exemplified by Kossman *et al.* who teach

fragments containing anti-sense regions to target two different genes in the starch synthesis pathway (see p. 9, Fig. 4, p. 24, and throughout).

Thus, given the teaching of Hitz *et al.* that foods having increased oleic acid and increased stearic acid would both be desirable food stuffs, and given the transgenic plants provided by Lightner *et al.* in view of Zwick *et al.*, it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have modified the transgenic plant taught by Lightner *et al.* in view of Zwick *et al.* so as to have also included the an isolated nucleic acid fragment encoding a corn delta-9 stearyl ACP desaturase wherein said desaturase has an amino acid sequence identity of 90% based on the clustal method of alignment when compared to SEQ ID NO: 9 taught by Zwick *et al.*, and to then use this transgenic plant in a method of feeding animals. One would have been motivated to create such a plant to obtain the benefit of both high oleic and high stearic fatty acids in the same plant, and one would have been further motivated to include the two genes within the same construct by the exemplification of an analogous construct as taught by Kossman *et al.* One would have been motivated to use such a plant in a feeding method by the teachings of Hitz *et al.* who teach the benefits of both types of consuming seeds with both types of fatty acids.

11. Claims 173, 175 and 176 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hitz *et al.* in view of Lightner *et al.* and Zwick *et al.* as applied to claims 173 and 176 above, and further in view of both Kriz *et al.* (US 6307123) and Vasil *et al.* (US 5955330).

The rejected claims all include an embodiment drawn to a method of feeding an animal comprising feeding an animal a corn grain obtained from a transgenic corn plant comprising in its genome a chimeric gene comprising an first isolated nucleic acid fragment encoding a corn

delta-12 desaturase wherein said fragment has a nucleic acid sequence identity of at least 90% based on the Clustal method of alignment when compared to instant SEQ ID NO: 1, a second isolated nucleic acid fragment comprising a corn oleosin promoter consisting essentially of SEQ ID NO: 40, and a shrunken 1 intron/exon, wherein expression of the chimeric gene results in an altered corn oleic acid phenotype, and for only claim 175, further wherein the corn grain has an oil content in the range from about 6% to about 10% on a dry matter basis and further wherein said oil is comprised of not less than 60% oleic acid of the total oil content of the seed.

The teachings of Hitz *et al.* in view of Lightner *et al.* and Zwick *et al.* are applied to this rejection as they were previously applied to claims 173 and 176. These combined teachings do not provide a transgenic plant comprising a construct which further comprises a second isolated nucleic acid fragment comprising a corn oleosin promoter consisting essentially of SEQ ID NO: 40, and a shrunken 1 intron/exon, wherein expression of the chimeric gene results in an altered corn oleic acid phenotype.

Lightner *et al.* do further teach the use of seed specific promoters, and specifically suggest as a desirable promoter oleosin promoters (see p. 58).

Kriz *et al.* teach constructs for the production of transgenic plants which comprise the L3 corn oleosin promoter, (Figure 1, Col. 68-69, and SEQ ID NO: 2). The construct DV130, for example, contains the L3 promoter, and is given as SEQ ID NO: 2 (Col. 68, lines 24-25). Instant SEQ ID NO: 40 is identical to nucleotides 423-967 of SEQ ID NO: 2 taught by Kriz *et al.* (Kriz *et al.* further teach constructs which comprise fragments consisting essentially of instant SEQ ID NO: 39, 44, 45, 46, 47, 48, and 49). Kriz *et al.* also teach that transcription enhancers are useful within their constructs (Col. 15), and specifically suggest the maize shrunken 1 gene enhancer

element. Kriz *et al.* do not provide any further guidance regarding the shrunken 1 gene enhancer.

Vasil *et al.* teach the maize shrunken 1 gene enhancer and teach that first intron and exon of this gene are useful for enhancing the expression of heterologous genes (Col. 2-3 and throughout).

Therefore, it would have been *prima facie* obvious to have modified the constructs taught by Lightner *et al.* so as to have also included the corn oelolin L3 promoter taught by Kriz *et al.* and the maize shrunken 1 gene enhancer taught by Lightner *et al.*, and to have used such a construct to make a transgenic maize plant as taught by Lightner *et al.* in view of Zwick *et al.*, and to have used the plant in a method of feeding animals. The ordinary practitioner would have been motivated by the teachings provided by Lightner *et al.* to use an oleosin promoter, the provision of such a promoter by Kriz *et al.*, the specific suggestion of Kriz *et al.* to use the shrunken gene 1 enhancer, and the teachings of Vasil *et al.* of the enhancer and its benefits. With regard to the specific properties of the plants used in the method of claim 175, these properties would be a necessary property of the plant made by combining the teachings of Lightner *et al.* in view of Zwick *et al.* with the teachings Kriz *et al.* and Vasil *et al.*, especially in view of the fact that Lightner *et al.* teach methods for increasing the oleic acid content of seeds. Applicant is reminded that MPEP 2112.01 teaches "Where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a *prima facie* case of either anticipation or obviousness has been established. In re Best, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977). 'When the

PTO shows a sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not.”

Response to Remarks

New grounds of rejection are set forth in view of the extensive amendment to the claims. The instant remarks are moot in light of the new grounds of rejection.

The IDS has been considered. The signed 1449 is enclosed with this office action.

Conclusion

12. No claims are allowed.

13. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

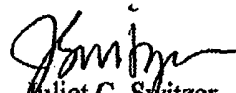
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14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Juliet C. Switzer whose telephone number is 703 306 5824. The examiner can normally be reached on Monday through Thursday, 9:00 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones can be reached on 703 308 1152. The fax phone numbers for the organization where this application or proceeding is assigned are 703 305 3592 and (703) 305-3014.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703 308 0196.

August 9, 2003


Juliet C. Switzer
Patent Examiner
AU 1634


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